



Lacrimedics, Inc.

APR 14 1997

K963708

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510(k) NOTIFICATION SUMMARY

Device name: Herrick Ultimate Punctum Plug

Device common name: Punctum Plug

Classification name: Punctum Plug (86LZU)

Predicate devices: Tapered-Shaft Punctum Plug (marketed by Eagle Vision and Ciba Vision)
Soft Plug™ (marketed by Oasis)
Punctum Plug (marketed by FCI Ophthalmics)

Device description: A flexible silicone ophthalmic device designed to fit and be retained in the punctum.

Device use: Used to enhance retention of eye fluids by occlusion of one or more punctum, reducing lacrimal flow. Useful for treatment of dry eye and other conditions where enhancement of tear retention is indicated.

Comparison to predicate devices:

Device name Features	Herrick Ultimate Punctum Plug (Lacrimedics)	Tapered Shaft Punctum Plug (Eagle Vision & Ciba)	Soft Plug (Oasis)	Punctum Plug (FCI Ophthalmics)
1. Indications claimed	Treatment of dry eye After eye surgery Enhance efficacy of medications Treatment of contact lens problems Adjunctive treatment aid	Treatment of dry eye	Treatment of dry eye After eye surgery Enhance efficacy of medications Treatment of contact lens problems Adjunctive treatment aid	(Not available)
2. Function	Causes occlusion of punctum, resulting in greater tear retention	Causes occlusion of punctum, resulting in greater tear retention	Causes occlusion of punctum, resulting in greater tear retention	Causes occlusion of punctum, resulting in greater tear retention
3. Design - length diameter (typical)	1.8 mm 0.8 mm	1.8 mm 0.7 mm	2.0 mm 0.9 mm	2.0 mm 0.8 mm
4. Material	Medical grade silicone	Medical grade silicone	Medical grade silicone	Medical grade silicone

Clinical tests: None

Adverse S&E information: None

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3-11-97
Date